

REMARKS

This application has been amended in a manner that is believed to place it in condition for allowance at the time of the next Official Action.

Claims 1-2 and 4-18 are pending in the present application. Claims 1-2 and 4-11 have been amended to address the formal matters raised in the outstanding Official Action. Claims 12-18 have been added. Support for claims 12-18 may be found in original claim 3 and in the present specification at page 8, line 1 to page 9, line 1.

In the outstanding Official Action, claims 1, 3 and 10 were objected to for containing several informalities. As noted above, claim 3 has been canceled. As to claims 1 and 10, it is believed that claims 1 and 10 have been amended to adapt these changes. Applicant notes with appreciation the suggestions by the Examiner as to how to overcome these objections. As a result, applicant believes that the claim objections have been obviated.

Claims 5 and 11 were rejected for allegedly not satisfying the requirements of 35 USC §101. The Official Action alleged that the claims recited a "use" without setting forth any steps involved in a process.

Claims 5 and 11 have been amended as method claims and recite a step involved in the recited method. As a result,

applicant believes that claims 5 and 11 satisfy the requirements of 35 USC §101.

Claims 1-11 were rejected under 35 USC §112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. This rejection is respectfully traversed.

In imposing the rejection, the Official Action alleged that claim 1 was indefinite for not reciting specific amounts of herbal ingredients. However, the Examiner is respectfully reminded that the test of definiteness is whether one skilled in the art would understand the scope of the claim when read in light of the specification. Indeed, if the scope of the subject matter embraced by a claim is clear and if the applicant has not otherwise indicated that he intends the claim to be of a different scope, then the claim particularly points out and distinctly claims the subject matter which the applicant regards as his invention. *In re Borkowski et al.*, 422 F.2d 904, 164 USPQ 242 (CCPA 1970); *In re Robins*, 429 F.2d 452, 166 USPQ 552 (CCPA 1977).

Upon reviewing claim 1, applicant believes that the claim is definite to one skilled in the art. While the claim may be broad because it does not provide precise amounts, claim 1 is plainly directed to a composition comprising caffeine, Guaraná, Yerba Maté, Eleutherococcus senticosus, Panax ginseng,

ginger, Glycyrrhiza glabra, ginkgo biloba and fructose. As a result, applicant believes that claim 1 is definite to one skilled in the art.

Claim 1 was also rejected for reciting the terms "caffeine" and "Guaraná caffeine". The Official Action alleged that it was unclear whether the composition comprised caffeine plus additional amounts of caffeine from Guarana, or caffeine plus Guarana extract that contains caffeine. As the Examiner is aware, Guarana may be used as an herbal supplement and contains large amounts of caffeine. Guarana is added to the claimed invention because it slowly releases caffeine and contains additional compounds that promote the alcohol and acetaldehyde metabolism to mitigate the effects of consuming alcohol. As a result, applicant believes that claim 1 is now definite to one skilled in the art.

Claims 2 and 4 were rejected for reciting the phrase "composition of claim 1 wherein an analgesic is present" and "composition of claim 1 wherein green tea is present". Applicant would like to thank the Examiner for his suggestion as to how to overcome this rejection and have amended the claims to recite the terminology --composition of claim 1, further comprising--.

Claims 3 and 10 were rejected for reciting the terms "preferably", "i.e." and "e.g.". As noted above, claim 3 has been canceled. Claim 10 has been amended so that these terms are

no longer recited in the claim. As a result, applicant believes that claim 10 is definite to one skilled in the art.

Claims 3, 10 and 11 were also rejected for reciting parenthetical phrases. The Official Action alleged that it was unclear whether the terminology inside the parentheses was a further limitation or simply alternative language. As noted above, claim 3 has been canceled. Claims 10 and 11 have been amended so that these parenthetical phrases have been eliminated. As a result, applicant believes that claims 10 and 11 are definite to one skilled in the art.

Claims 5 and 11 were rejected for reciting the "use" of a composition without reciting any steps involved in a method/process. However, as noted above, claims 5 and 11 have been amended to recite methods. As a result, applicant believes that claims 5 and 11 are definite to one skilled in the art.

Claim 6 was rejected for reciting the phrase "may be". As suggested by the Examiner, the claim has been amended to delete the phrase "may be" for the term --is--. As a result, applicant believes that claim 6 is definite to one skilled in the art. Once again, applicant would like to thank the Examiner for his suggestion as to how to overcome this rejection.

Claims 7, 8, 9 and 10 were rejected for reciting the phrases "aqueous product according to claim 1", "pharmaceutical product according to claim 1", "the dry components", and "adding the ingredients...and optionally ginkgo biloba". However, claims

7-10 have been amended so that these terms are no longer recited in the claims. As a result, applicant believes that claims 7-10 are definite to one skilled in the art.

Claims 1-2, 4-9 and 11 were rejected under 35 USC §103(a) as allegedly being unpatentable over BELL et al. 2003/0138520 with evidence provided by PARK et al. 2003/0026858 and SAWAGUCHI JP 62292725. This rejection is respectfully traversed.

The present invention is a composition designed for the stimulation of specific target metallo-enzymes in order to suppress and treat the effects resulting from the consumption of ethanol and/or its metabolites. Although the ingredients contained in the BELL et al. publication are described independently and recited in an exhaustive list of ingredients, applicant believes that BELL et al. fail to disclose or suggest the claimed combination of ingredients.

BELL et al. disclose confectionery products containing active nutritive/functional ingredients. While the publication lists a substantial number of ingredients, the publication does not suggest to one skilled in the art to modify the teachings of the publication to obtain the claimed combination. Indeed, most of the ingredients listed by BELL et al. are inhibitors of alcohol and acetaldehyde metabolizing enzymes. For example, sulphur- and heterocyclic containing ingredients are known to be powerful inhibitors of liver alcohol dehydrogenase activity

(LADH). The presence of these types of ingredients would significantly inhibit and negatively affect the alcohol metabolism of an individual. As a result, it is believed that BELL et al. actually teach away from the claimed invention.

Although the PARK et al. and SAWAGUCHI publications describe the effects of ginseng and other components, neither publication discloses or suggests the claimed combination or the unique synergistic stimulating effect resulting from the claimed combination. As a result, applicant believes that the publications fail to remedy the deficiencies of BELL et al. Indeed, as set forth in *In re Kotzab*, 217 F.3d 1365, 1369-70, 55 USPQ2d 1313, 1316 (Fed. Cir. 2000) (citations omitted):

A critical step in analyzing the patentability of claims pursuant to §103(a) is casting the mind back to the time of the invention, to consider the thinking of one of ordinary skill in the art, guided only by the prior art references and the then-accepted wisdom in the field. A close adherence to this methodology is especially important in cases where the very ease with which the invention can be understood may prompt one "to fall victim to the insidious effect of a hindsight syndrome wherein that which only the invention taught is used against his teacher.

To establish obviousness based on a combination of the elements disclosed in the prior art, there must be some motivation, suggestion or teaching of the desirability of making the specific combination that was made by the applicant.

In other words, the mere possibility that the prior art could be modified in a manner consistent with applicant's specification and claims is not the standard for imposing an

obviousness rejection. Indeed, the fact that the prior art could possibly be modified in such a manner does not make the modification obvious unless the prior art suggests the desirability of the modification. *In re Gordon*, 733 F.2d 900, 902, 221 USPQ 1125, 1127 (Fed. Cir. 1984).

Thus, in view of the above, applicant believes that the proposed combination of references fails to render obvious the claimed invention.

Moreover, while the Official Action alleges that the adjustment of particular parameters such as amounts would be obvious to one skilled in the art, applicant believes that the cited publications fail to provide the necessary motivation to combine and modify the teachings of BELL et al., PARK et al. and SAWAGUCHI to obtain the claimed invention. Indeed, a particular parameter variable must first be recognized as a result-effective variable, i.e., a variable which achieves a recognized result, before the determination of the parameter variable would be characterized as routine or obvious. *In re Antonie*, 559 F.2d 618, 195 USPQ 6 (CCPA 1977). See also *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980). As the above-identified publications fail to characterize the claimed parameters as discussed in the Official Action as result-effective variables, applicant believes that the Official Action fails to satisfy its burden in showing that the combination and recited amounts are merely a matter of optimization.

Thus, in view of the above, applicant requests that the rejection of BELL et al. as evidenced by PARK et al. and SAWAGUCHI be withdrawn.

In view of the present amendment and the foregoing remarks, therefore, applicant believes that the present application is in condition for allowance at the time of the next Official Action, with claims 1-2 and 4-18, as presented. Allowance and passage to issue on that basis is respectfully requested.

The Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 25-0120 for any additional fees required under 37 C.F.R. § 1.16 or under 37 C.F.R. § 1.17.

Respectfully submitted,

YOUNG & THOMPSON



---

Philip Dubois, Reg. No. 50,696  
745 South 23<sup>rd</sup> Street  
Arlington, VA 22202  
Telephone (703) 521-2297  
Telefax (703) 685-0573  
(703) 979-4709

PD/lrs